



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: James, Kenneth D. Ph.D., et al.

Group Art Unit: 1642

Serial Number: 10/723,933

Confirmation No. 9468

Filed: November 26, 2003

For: NATRIURETIC COMPOUNDS, CONJUGATES, AND USES THEREOF

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 CUSTOMER NO. 24,239

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56 AND 37 C.F.R. § 1.97

It is respectfully requested that the document listed on the attached Form PTO/SB/08A be considered by the Patent and Trademark Office in the above-referenced application and made of record therein. A full text copy of the relevant document is enclosed. This information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last.

Respectfully submitted,

By:

William A. Barrett
Registration No. 42,296
Attorney for Applicants
Moore & Van Allen, PLLC
2200 West Main Street, Suite 800
Durham, NC 27705

Phone: 919-286-8000

Facsimile: 919-286-8199

August 20, 2004

Date

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the US Postal Service as first class mail on August 20, 2004, in an envelope addressed to Commissioner of Patents, PO Box 1450, Alexandria, VA 22313-1450

Matrina Holland

Substitute or form 1449A/PTO

Sheet

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of

4

1

| Complete if Known | | | | | |
|------------------------|-------------------------|--|--|--|--|
| Application Number | 10/723,933 | | | | |
| Filing Date | November 26, 2003 | | | | |
| First Named Inventor | James, Kenneth D. Ph.D. | | | | |
| Art Unit | 1642 | | | | |
| Examiner Name | | | | | |
| Attorney Docket Number | 01/1811-205 108 | | | | |

| | | | U.S. PATENT | DOCUMENTS | |
|-----------|------------------|--|--------------------------|-----------------------------|---|
| Examiner | Cite | Document Number | Publication Date/ | Name of Patentee or | Pages, Columns, Lines, Where |
| Initials' | No. ¹ | Number-Kind Code ² (if known) | Issue Date MM-DD-YYYY | Applicant of Cited Document | Relevant Passages or Relevant Figures Appear |
| | B1 | US- 6,713,454 | 03/30/2004 | Ekwuribe et al. | , <u>, , , , , , , , , , , , , , , , , , </u> |
| | B2 | US- 6,713,452 | 03/30/2004 | Ekwuribe et al. | |
| | В3 | US- 6,703,381 | 03/09/2004 | Ekwuribe et al. | |
| | B4 | US-6,638,906 | 10/28/2003 | Ekwuribe | |
| | B5 | US- 6,586,396 | 07/01/2003 | Seilhamer et al. | |
| | B6 | US- 6,583,128 | 06/24/2003 | Ekwuribe et al. | |
| | B7 | US- 6,541,508 | 04/01/2003 | Ekwuribe et al. | |
| | B8 | US- 6,309,633 | 10/30/2001 | Ekwuribe et al. | |
| | B9 | US- 6,191,105 | 02/20/2001 | Ekwuribe et al. | |
| 1 | B10 | US- 6,117,644 | 09/12/2000 | DeBold | |
| | B11 | US- 6,037,145 | 03/14/2000 | Yabuta et al. | |
| | B12 | US- 6,028,055 | 02/22/2000 | Lowe et al. | |
| | B13 | US- 5,681,811 | 10/28/1997 | Ekwuribe | |
| | B14 | US- 5,674,710 | 10/07/1997 | Seilhamer et al. | • |
| | B15 | US- 5,438,040 | 08/01/1995 | Ekwuribe | |
| | B16 | US- 5,359,030 | 10/25/1994 | Ekwuribe | |
| | B17 | US- 5,114,923 | 05/19/1992 | Seilhamer et al. | |
| | B18 | US- 5,037,741 | 08/06/1991 | lacobucci | |
| | B19 | US-4,489,065 | 12/18/1984 | Walton et al. | |
| | B20 | US-2004/0152769 | 08/05/2004 | Ekwuribe et al. | |
| | B21 | US-2004/0092449 | 05/13/2004 | Ekwuribe | |
| | B22 | US-2004/0091452 | 05/13/2004 | Ekwuribe et al. | |
| | B23 | US-2004/0063630 | 04/01/2004 | Schreiner | |
| | B24 | US-2004/0038866 | 02/26/2004 | Soltero et al. | |
| | B25 | US-2004/0017387 | 01/29/2004 | Soltero et al. | |
| | B26 | US-2003/0229010 | 12/11/2003 | Ekwuribe | |
| | B27 | US-2003/0229006 | 12/11/2003 | Ekwuribe | |
| | B28 | US-2003/0228652 | 12/11/2003 | Radhakrishnan et al. | |
| | B29 | US-2003/0228275 | 12/11/2003 | Ekwuribe et al. | |
| | B30 | US-2003/0144468 | 07/31/2003 | Ekwuribe et al. | |
| | B31 | US-2003/0109420 | 06/12/2003 | Valkirs et al. | |
| | B32 | US-2003/0083232 | 05/01/2003 | Soltero et al. | |
| | B33 | US-2003/0069170 | 04/10/2003 | Soltero et al. | |
| | B34 | US-2003/0060606 | 03/27/2003 | Ekwuribe et al. | |
| | B35 | US-2003/0027995 | 02/06/2003 | Ekwuribe et al. | |
| | B36 | US-2003/0027748 | 02/06/2003 | Ekwuribe et al. | |
| | B37 | US-2003/0025559 | 02/06/2003 | Goldenberg | |
| | B38 | US-2003/0004304 | 01/02/2003 | Ekwuribe et al. | |

| Examiner | Date | |
|-----------|------------|----------|
| Signature | Considered | <u> </u> |

| Substitute for form 1449A/PTO | | Complete if Known | | | | |
|-------------------------------------|------------------------|-------------------|-----|------------------------|-------------------------|--|
| Cabanan | | | | Application Number . | 10/723,933 | |
| SUPPLEMENTAL INFORMATION DISCLOSURE | | | | Filing Date | November 26, 2003 | |
| | | | | First Named Inventor | James, Kenneth D. Ph.D. | |
| | STATEMENT BY A | APPLIC | ANT | Art Unit | 1642 | |
| | (use as many sheets as | s necessar | y) | Examiner Name | | |
| Sheet | 2 | of | 4 | Attorney Docket Number | 014811-205.108 | |

| | FOREIGN PATENT DOCUMENTS | | | | | | | |
|-----------------------|--------------------------|--|-----------------------------|--|---|----------------|--|--|
| Examiner Initials' | Cite No.1 | Foreign Patent Document Country Code ³ –Number ⁴ –Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ | | |
| •- | B39 | WO 02/083913 A1 | 10/24/2002 | Biosite Diagnostics, Inc. | | | | |
| | B40 | WO 01/45742 | 06/28/2001 | Samyang Corporation | | | | |
| | B41 | WO 01/16295 | 03/08/2001 | The Regents of the University of California | | | | |
| | B42 | WO 99/22235 | 05/06/1999 | Shionogi & Co., Ltd. | | | | |
| | B43 | WO 98/45329 | 10/15/1998 | Novo Nordisk A/S | | | | |
| | B44 | WO 98/17690 | 04/30/1998 | Genentech, Inc. | | | | |
| | B45 | WO 98/00183 A2 | 01/08/1998 | Shaw, Robert Francis | | | | |
| | B46 | WO 98/00183 A3 | 01/08/1998 | Shaw, Robert Francis | | | | |
| | B47 | WO 97/34626 | 09/25/1997 | Creative Biomolecules, Inc., et al. | | | | |
| | B48 | WO 95/28952 | 11/02/1995 | Haemopep Pharma GmbH | | | | |
| | B49 | WO 93/24531 | 12/09/1993 | Dzieglewska, Hanna, Eva | | | | |
| | B50 | WO 91/09627 | 07/11/1991 | Hedner, Thomas, et al. | | | | |
| | B51 | WO 91/00292 | 01/10/1991 | Genentech, Inc. | | | | |
| | B52 | EP 0 385 476 B1 | 07/12/1995 | Daiichi Pure Chemicals Co., et al. | | | | |
| | B53 | EP 0 385 476 B2 | 09/22/1999 | Shionogi & Co., Ltd. | | | | |
| | B54 | EP 0 418 308 B1 | 08/16/1999 | Scios Nova Inc. | | _ | | |
| • | B55 | EP 0 479 948 B1 | 08/26/1998 | Genentech, Inc. | | | | |
| | B56 | EP 0 542 863 B1 | 11/26/1997 | Scios Inc. | | | | |
| | B57 | EP 0 700 995 B1 | 03/13/1996 | Suntory Limited | | | | |
| | B58 | EP 0 725 638 B1 | 08/14/1996 | The University of Sheffield | | | | |
| | | | | | | | | |

| Examiner | Date | |
|-----------|----------------|--|
| Signature | Considered | |
| | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | Substitute for form 1449B/PTO | | | | Complete if Known |
|------------|---|-----------|-----|------------------------|-------------------------|
| Substitute | | | | Application Number | 10/723,933 |
| | SUPPLEMENTA | AL | | Filing Date | November 26, 2003 |
| | INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | First Named Inventor | James, Kenneth D. Ph.D. |
| | | | | Art Unit | 1642 |
| | | | | Examiner Name | |
| | (use as many sheets as ned | cessa | ny) | | |
| Sheet | 3 | of | 4 | Attorney Docket Number | 014811-205.108 |

| | | NON PATENT LITERATURE DOCUMENTS | |
|-----------------------|--------------------------|---|----|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | B59 | Levin, Ellis R., et al. "Natriuretic Peptides," [Mechanisms of Disease] The New England Journal of Medicine, Vol. 339 No. 5, pp 321-328, July 30, 1998 | |
| | B60 | Jin, Hongkui, et al., "Novel analog of atrial natriuretic peptide selective for receptor-A produces increased diuresis and natriuresis in rats," <i>J. clin. Invest.</i> , Vol. 98, No. 4, pp. 969-976, August 1996 | |
| | B61 | De las Fuentes, Lisa, et al., "Myocardial fatty acid metabolism independent predictor of left ventricular mass in hypertensive heart disease," <i>Hypertension</i> , pp. 83-87, January 2003 | |
| | B62 | Matsuo, Hisayuki, "Discovery of a natriuretic peptide family and their clinical application," Can J. Physiol. Pharmacol. 79, pp. 736-740, 2001 | |
| | B63 | Schirger, John A., et al., "Endothelin A Receptor Antagonism in Experimental Congestive Heart Failure Results in Augmentation of the Renin-Angiotensin System and Sustained Sodium Retention," Circulation, pp. 249-254, January 20, 2004 | |
| | B64 | . Maniu, Calin V., et al., "Hemodynamic and Humoral Effects of Vasopeptidase Inhibition in Canine Hypertension," <i>Hypertension</i> , pp. 528-534, October 2002 | |
| | B65 | Chari, Y.T., et al., "Load Versus Humoral Activation in the Genesis of Early Hypertensive Heart Disease," Circulation, pp. 215-220, July 10, 2001 | |
| | B66 | Chen, Horng H., et al., "Endogenous Natriuretic Peptides Participate in Renal and Humoral Actions of Acute Vasopeptidase Inhibition in Experimental Mild Heart Failure," <i>Hypertension</i> , pp. 187-191, August 2001 | |
| | B67 | Cataliotti, Alessandro, et al., "Brain Natriuretic Peptide Enhances Renal Actions of Furosemide and Suppresses Furosemide-Induced Aldosterone Activation in Experimental Heart Failure," Circulation, pp. 1680-1685, April 6, 2004 | |
| | B68 | Boerrigter, MD, Guido,et al., "Cardiorenal and Humoral Properties of a Novel Direct Soluble Guanylate Cyclase Stimulator BAY 41-2272 in Experimental Congestive Heart Failure," Circulation, pp. 686-689, February 11, 2003 | |
| | B69 | Hart, Chari Y., et al., "Differential effects of natriuretic peptides and NO on LV function in heart failure and normal dogs," <i>Am J Physiol Heart Circ. Physiol</i> , 281: H146-H154, 2001 | |
| | B70 | Lisy, MD, Ondrej, et al., "Mechanical Unloading Versus Neurohumoral Stimulation on Myocardial Structure and Endocrine Function In Vivo," <i>Circulation</i> , pp. 338-343, July 18, 2000 | |
| | B71 | Ishikawa, Hirokazu, et al., "Production of Human Calcitonin in <i>Escherichia coli</i> from Multimeric Fusion Protein," <i>Journal of Fermentation and Bioengineering</i> , Vol, 82, No. 2, pp. 140-144, 1996 | |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Substitute for form 1449B/PTO | | | | Complete if Known | | |
|-------------------------------|---|---------|-----|------------------------|-------------------------|--|
| | | | | Application Number | 10/723,933 | |
| | SUPPLEMEN' | TAL | | Filing Date | November 26, 2003 | |
| | INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | First Named Inventor | James, Kenneth D. Ph.D. | |
| | | | | Art Unit | 1642 | |
| | | | | Examiner Name | | |
| • | (use as many sheets as a | necessa | ry) | | | |
| Sheet | 4 | of | 4 | Attorney Docket Number | 014811-205.108 | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--------------------------|---|----|--|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² | | |
| | B72 | Raingeaud, J., et al., "Production, analysis and bioactivity of recombinant vasoactive intestinal peptide analogs," <i>Biochimie</i> , 78, pp. 14-25, 1996 | | | |
| | B73 | Lennick, Michael, et al., "High-level expression of α -human atrial natriuretic peptide from multiple joined genes in <i>Escherichia coli</i> ," <i>Gene</i> , 61, pp. 103-112, 1997 | | | |
| | B74 | Kempe, Tomas, et al., "Multiple-copy genes: production and modification of monomeric peptides from large multimeric fusion proteins," <i>Gene</i> , 39, pp. 239-245, 1985 | | | |
| | B75 | Wang, Jun, et al., "Overexpression and purification of recombinant atrial natriuretic peptide using hybrid fusion protein REF-ANP in Escherichia coli," Protein Expression and Purification, 28, pp. 49-56, 2003 | | | |
| | B76 | Jungk, Steven John, et al., "Efficient Synthesis of C-Pivot Lariat Ethers. 2-(Alkoxymethyl)-1,4,7,10,13,16-hexaoxacycloota-decanes," <i>J. Org. Chem</i> , 48, pp. 1116-1120, 1983 | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |